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Ortho Molecular Products Inc. 3017 Business Park Drive P.O. Box 1060 Stevens Point, WI 54481 715.342.9881 Phone 800.332.2351 715.342.9866 Fax orthomolecular products.com

Office of Special Nutritional (HFS-450) Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached labels on page 2).

Name of Manufacturer: Ortho Molecular Products, Inc.

3017 Business Park Drive

P.O. Box 1060

Stevens Point, WI 54481

Statement Text: Gastrointestinal Support, Immune System

Dietary Ingredients: Black Walnut Hulls, Sweet Wormwood (Aerial Portions), Slippery Elm Bark, Garlic Bulb, Senna Leaf, Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

Dietary Supplement Name: Ortho Worcid Forte

As required, enclosed are two photocopies of this notification.

I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,

Melissa Slager

Document Control / Training Manager

Ortho Molecular Products

975 0162 LET 16291



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Attachment of Ortho Worcid Forte Labels

Suggested Use As a dietary supplement, 1-2 capsules three times per day or as recommended by your health care professional. Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. This product contains the following potential allergen: Tree Nuts Do not consume this product if you are pregnant or nursing. Consult your physician for further information. As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used." Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion. Keep container tightly closed. Store at room temperature. Keep out of reach of Children

This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal are missing or damaged.



Label ID L-0MP100-816090-B

Also Excellent for:

PRODUCTS Because Efficacy Matters®

Ortho Worcid Forte



Supplement Facts

Serving Size: 1 Capsule Servings Per Container: 90

Amount Per 1 capsule contains Serving Proprietary Blend: Elack Walnut Hulls 580 mg Sweet Wormwood (Aenal Portions) Silppery Eirn Bark Garlic Bulb Senna Leaf

* % Daily Value not established Other Ingredients: Natural vegetable capsules, This product may contain one or more of the following: Ascorbyl Palmitate,

Magnesium Stearate, Microcrystalline Cellulose and Silicon Dioxide. Milg. by Ortho Molecular Products, Inc. 3017 Business Park Drive Stevens Point, WI 54481